

### Hazard Analysis Template

System	Hazard Description	Risk before Mitigation Measures			Risk Elimination or Mitigation Measures	Risk After Mitigation Measures			Corrective Actions
		Severity	Likelihood	Risk Hazard Index		Severity	Likelihood	Risk Hazard Index	
Wearable HIVE Recording Module	Intermittent failure to transmit EMG packets causes unintended prosthetic movements	1 Negligible	4 Probable	4	1. Real-time status information will indicate corrupted or dropped packets or degraded link quality 2. Stop movement command will be sent to prosthetic to prevent unintended movements 3. Wireless communication automatically resumes when link is clear	1 Negligible	3 Occasional	3	1. Antennae may need to be re-positioned
	Repeated failure to transmit EMG packets causes unintended prosthetic movements	1 Negligible	2 Remote	2	1. Real-time status information will indicate corrupted or dropped packets or degraded link quality 2. Stop movement command will be sent to prosthetic to prevent unintended movements 3. Wireless communication session is aborted	1 Negligible	2 Remote	2	1. If connected, disconnect neural sensing module from patient 2. Examine error logs and status information 3. If the root cause is determined to be a component failure or cannot be identified, discontinue device from study
	Electrical harm to patient	3 Serious	1 Improbable	3	1. The neural sensing module, which connects to the [REDACTED] electrodes will be leakage current tested to comply with 14708-1 standards for implantable devices. This is a more rigorous standard than 60601-1 for external devices.	3 Serious	1 Improbable	3	1. If connected, disconnect neural sensing module from the patient 2. Remove device from patient 3. Discontinue from use in study
	Patient discomfort due to heat	2 Minor	1 Improbable	2	1. The neural sensing module is a low power consumption device and therefore extremely unlikely to generate enough heat to cause discomfort. Similar devices from our lab have consumed <40mW. Furthermore, the PCB will be separated from direct body contact by the plastic enclosure.	2 Minor	1 Improbable	2	1. If connected, disconnect neural sensing module from the patient 2. Remove device from patient 3. Discontinue from use in study
	Battery hazards	4 Critical	1 Improbable	4	1. The neural sensing module receives power from the NNP power module, which has been tested under investigational device exemption at Case Western Reserve University. 2. The wearable HIVE recording module will only be used in a supervised laboratory environment and handled by trained study personnel. In an abundance of caution, the power module will be charged in between uses when the neural sensing module is disconnected from the patient.	4 Critical	1 Improbable	4	1. If connected, disconnect neural sensing module from patient 2. Discontinue from use in study
	Device malfunction due to electrostatic discharge	2 Minor	3 Occasional	6	1. Intan amplifier contains internal diodes to protect from mild ESD events 2. The wearable HIVE recording module will only be used in a supervised laboratory environment and handled by trained study personnel	2 Minor	2 Remote	4	1. If connected, disconnect neural sensing module from patient 2. Inspect neural sensing module, examine error logs and status information 3. If the root cause is determined to be a component failure or cannot be identified, discontinue device from study
	Neural sensing module places mechanical strain on electrode leads	2 Minor	3 Occasional	6	1. [REDACTED] connector system provides strain relief 2. The neural sensing module is a compact and lightweight device. It will only be handled and connected to the patient by trained study personnel	2 Minor	1 Improbable	2	1. Reposition neural sensing module to reduce any tension in adapter cable